



医疗器械质量管理体系 认证证书

注册号: UKZB21MD20035R0S

统一社会信用代码: 91330108MA28UEWC1M

兹 证 明

杭州比格飞序生物科技有限公司

医疗器械质量管理体系符合

ISO13485:2016 idt YY/T 0287-2017, 适用于

样本保存液、全自动核酸提取纯化仪、核酸提取或纯化试剂、基因扩增仪的设计开发、生产和销售; 新型冠状病毒(SARS-CoV-2)抗原快速检测试剂盒(胶体金)、新型冠状病毒(SARS-COV-2)中和抗体快速检测试剂盒(胶体金)、新型冠状病毒(SARS-COV-2)核酸检测试剂盒(荧光 PCR 法)(CE 认可国家); 实时荧光定量 PCR 分析仪的设计开发、生产和销售(CE,FDA 认可国家)

注册地址: 浙江省杭州市富阳区银湖街道富闲路9号银湖创新中心6号3层310室

经营地址: 浙江省杭州市余杭区仓前街道龙泉路22号2-8101单元, 浙江省杭州市富阳区银湖街道富闲路9号银湖创新中心6号3层310室

初次发证日期: 2021年05月25日

本次发证日期: 2022年02月28日

证书有效期至: 2024年05月24日

新世纪检验认证有限责任公司

总经理:



BCC地址: 北京市西城区国英园1号楼11层1101室

本证书在国家规定的各行政许可、资质许可有效期内使用有效

获证组织必须定期接受监督审核并经审核合格,此证书方继续有效。

证书有效性可通过网站: www.bcc.com.cn 查询, 也可二维码查询

本证书信息可在国家认监委网站 www.cnca.gov.cn 查询

UKAS认可BCC的范围: ISO13485





CERTIFICATE OF MEDICAL DEVICE QUALITY MANAGEMENT SYSTEM CERTIFICATION

Certificate No.UKZB21MD20035R0S

Unified social credit code:91330108MA28UEWC1M

This is to Certify that the Medical Device Quality Management System of

HANGZHOU BIGFISH BIO-TECH CO.,LTD

is in conformity with

ISO13485:2016 idt YY/T 0287-2017 Standard, applies to

DESIGN, DEVELOPMENT, PRODUCTION AND SALES OF SAMPLE PRESERVATION LIQUID,
AUTOMATIC NUCLEIC ACID EXTRACTION AND PURIFICATION INSTRUMENT, NUCLEIC ACID
EXTRACTION OR PURIFICATION REAGENT, GENE AMPLIFICATION INSTRUMENT; NOVEL
CORONAVIRUS RAPID DETECTION KIT FOR ANTIGEN (COLLOIDAL GOLD), NOVEL
CORONAVIRUS RAPID DETECTION KIT FOR NEUTRALIZING ANTIBODY (COLLOIDAL GOLD),
NOVEL CORONAVIRUS NUCLEIC ACID TEST KIT FOR SARS-COV-2 (FLUORESCENCE PCR) (CE
APPROVED COUNTRIES); DESIGN, DEVELOPMENT, PRODUCTION AND MARKETING OF REAL-
TIME FLUORESCENCE QUANTITATIVE PCR ANALYZER (CE,FDA APPROVED COUNTRIES)

REGISTERED ADDRESS:ROOM 310, FLOOR 3, NO. 6, YINHU INNOVATION CENTER, NO. 9, FUXIAN
ROAD, YINHU STREET, FUYANG DISTRICT, HANGZHOU CITY, ZHEJIANG PROVINCE, P.R.C.
OPERATION ADDRESS:UNIT 2-8101, NO. 22, LONGQUAN ROAD, CANGQIAN STREET, YUHANG
DISTRICT, HANGZHOU, PROVINCE, P.R.C. ZHEJIANG, ROOM 310, FLOOR 3, NO. 6, YINHU
INNOVATION CENTER, NO. 9, FUXIAN ROAD, YINHU STREET, FUYANG DISTRICT, HANGZHOU,
ZHEJIANG PROVINCE, P.R.C.

Date of Initial Issuance:May. 25, 2021

Date of Issuance:Feb. 28, 2022

Date of Expiration:May. 24, 2024

BCC Inc.

President:



BCC Address: Room 1101, Floor 11, Building 1, Guoyingyuan, Xicheng District, Beijing, P.R.C.
This certificate is valid within state - specified validities of administrative and qualification licensing.
The effectiveness of this certificate shall be maintained by regular surveillance audit,
the validity of the certificate can be inquired through www.bcc.com.cn or by QR code.
The information of this certificate available for inquiry on CNCA's website: www.cnca.gov.cn.
Accreditation by UKAS is granted to BCC for providing audits and certifications of ISO13485

